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From: Laura Haburay Bishop
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Date: August 13, 2004
Pages: Six (6), Including Cover Page
Re: Substance of Interview After Final for **S/N 09/943,550**, filed August 30, 2001;
Attorney Docket No.: AB-146U

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MESSAGE:

Please find attached:

- Substance of Interview After Final Rejection Under 37 CFR 1.133, responding to an Interview Summary mailed July 14, 2004, for Application **Serial Number 09/943,550.** (5 pages)

Thank you.

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Docket No.: AB-146U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	09/943,550
Conf. No.:	9637
Applicants:	Harrison, et al.
Filed:	August 30, 2001
TC/A.U.:	3762
Examiner:	Oropeza, Frances P.
Title:	Systems and Methods for Modulation of Circulatory Perfusion by Electrical and/or Drug Stimulation
Docket No.:	AB-146U
Customer No.:	23845

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Substance of Interview AFTER FINAL
EXPEDITED HANDLING REQUESTED

Substance of Interview After Final Rejection Under 37 CFR 1.133

Dear Examiner:

A telephonic interview was held on July 8, 2004 relating to the final Office action mailed April 9, 2004 (Paper #7) for the above-identified application, in which claims 1-6, 9-12, 19 and 21-28 were rejected. This paper is responsive to the requirements set forth in the Examiner's Interview Summary mailed July 14, 2004.

The interview participants were Examiner Frances P. Oropeza and applicants' representative, Laura H. Bishop. No exhibits were shown and no demonstration conducted. The claims discussed were independent claims 1 and 21. The prior art discussed was US 6464687 to Ishikawa et al. and US 6571127 to Ben-Haim et al.

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In the Office action mailed April 9, 2004, independent claims 1 and 21 were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Ishikawa et al. (US 6464687) in view of Ben-Haim et al (US 6571127). Applicants respectfully traversed this rejection in light of the remarks submitted in a response filed July 9, 2004 and as discussed with the Examiner during the telephonic interview conducted July 8, 2004.

As discussed during the interview and in the response, independent claim 1 covers implanting a device to apply electrical stimulation in a first area of a patient in order to modulate circulatory perfusion in a second area that is targeted for medication delivery, and modifying the electrical stimulation to cause *hypoperfusion to restrict perfusion of the medication in the second area*. Independent claim 21 covers implanting a device to apply electrical stimulation in a first area of a patient in order to modulate circulatory perfusion in a second area that is targeted to receive medication delivered to a third area, and modifying the electrical stimulation to cause *hyperperfusion to focus the medication* in the second area. Applicants' representative argued that a person of ordinary skill in the art would not have been motivated by Ishikawa et al. and Ben-Haim et al. to implant a device to apply electrical stimulation to cause hypoperfusion or hyperperfusion to keep or direct drugs to a certain location within the body.

The Examiner pointed out that Ishikawa et al. teach that their device "provides an actuator function to stimulate the tissues into which drugs are to be released" (col. 29 @ 35-36) and that "[a] remote control... may be implanted in the body proximate to or remoted [sic] from the ball 110" (col. 7 @ 7-10). Applicants' representative maintained that this fails to teach the type of stimulation that should be used, and therefore fails to suggest that the stimulation should be used to cause hypoperfusion or hyperperfusion to keep or direct the drugs to a certain location within the body. (Note that, in the Office action dated April 9, 2004, the Examiner indicated that Ishikawa et al. do not disclose "the method seeking to cause

hypoperfusion/hyperperfusion." Applicants submitted that Ishikawa et al. therefore *cannot* disclose that "perfusion of [a] medication is restricted due to the hypoperfusion" (claim 1) or that "medication is focused into [an] area of the patient due to the hyperperfusion" (claim 21).)

The Examiner stated in "Continuation of Substance of Interview" dated July 14, 2004, that "the independent claim limitations of providing two areas of treatment, one area being electrically stimulated to alter circulatory perfusion at a second area, creating hypoperfusion of the medication at the second area....were acknowledged as being taught by the references...." Applicant respectfully clarifies that neither reference teaches or suggests using stimulation-induced hypo- or hyperperfusion *to restrict or focus medication* to targeted tissue. That is, neither reference teaches or suggests that "perfusion of [a] medication is restricted due to the hypoperfusion" as provided in claim 1, and neither reference teaches or suggests that "medication is focused into [an] area of the patient due to the hyperperfusion" as provided in claim 21. Applicants' representative points out that, even if Ben-Haim et al. taught "electrical stimulation and drugs to change tissue profusion between hypoperfusion and hyperperfusion" this falls short of using stimulation-induced hypo- and hyperperfusion *to restrict or focus medication* to targeted tissue, as covered by independent claims 1 and 21.

For instance, while Ben-Haim et al. mention that "[e]lectrically induced relaxation of blood vessels may be used instead of or in addition to pharmaceuticals" (col. 5 @ 19-21), this does not teach or suggest stimulus-induced hypoperfusion where "medication is restricted due to the hypoperfusion" or hyperperfusion where "medication is focused...due to the hyperperfusion." Ben-Haim et al. also mention "reducing the preload and/or the afterload on the heart [to] allow better perfusion of the ischemic tissues" (col. 5 @ 24-29). This also fails to teach or suggest stimulation-induced hypo- or hyperperfusion *to restrict or focus medication* as claimed in independent claims 1 and 21, respectively.

Ben-Haim et al. note, "various embodiments of the present invention...can be used in conjunction with drug therapies, with a synergistic interaction and/or to allow a reduced dose of drug to produce a desired effect and/or to allow increased dosages of drugs to be used, while limiting their adverse side effects using electrical control" (col 15 @ 39-45). Yet, there is no discussion or suggestion of *stimulation to create hypo- or hyperperfusion to keep or direct drugs to a certain location within the body.* There is no suggestion that the "desired effect" is to keep or direct drugs to a certain location within the body, and no suggestion that the "electrical control" of "adverse side effects" is achieved via hypoperfusion or hyperperfusion *to keep or direct the drugs to a certain location* within the body.

In summary, as Ben-Haim et al. and Ishikawa et al. fail to teach or suggest stimulation-induced hypo- and hyperperfusion to restrict or focus medication, these references fall short of meeting or suggesting all elements of independent claims 1 and 21. More specifically, these patents, even in combination with the other cited art, do not show or suggest "applying [a] stimulus...to modulate circulatory perfusion in [an] area of the patient...targeted to receive medication...to cause hypoperfusion...wherein perfusion of the medication is restricted due to the hypoperfusion" (claim 1) or "to cause hyperperfusion...wherein the medication is focused...due to the hyperperfusion" (claim 21).

As agreed in the July 8, 2004 interview, these and other arguments were recorded in an After Final Response filed July 9, 2004. Reconsideration of the rejection of independent claims 1 and 21 is respectfully requested. All of the other pending claims depend directly or indirectly from independent claim 1 or 21. An indication of allowability of all pending claims, claims 1-6, 9-12, 19 and 21-28, is earnestly solicited.

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The Examiner is invited to telephone the undersigned, Laura Bishop, at her convenience should any issues remain after consideration of the telephonic interview, this submission, and the July 9, 2004 response to Office action, in order to permit early resolution of the same.

Respectfully Submitted,

2004 Aug 13
Date

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